

REMARKS

This paper is a Response to the Office Action mailed December 22, 2008. Claims 111 to 130, and 133 to 154 are under consideration. Claims 117 to 119 and 135 to 154 have been cancelled herein without prejudice. Applicants maintain the right to prosecute the cancelled claims in any related application claiming the benefit of priority of the subject application. Accordingly, upon entry of this paper claims 111 to 116, 120 to 130, 133 and 134 are under consideration.

Regarding the Claim Amendments

The amendments to the claims are supported throughout the specification. In particular, the amendment to claim 121 to recite “and” instead of “or” in reference to the predicted CDR sequences is supported, for example, at page 4, line 28, to page 5, line 10, and page 5, line 21, to page 6, line 4. The amendment to claim 124 to delete reference to the particular fragments is supported, for example, at page 4, line 28, to page 5, line 1. Thus, as the claim amendments are supported by the specification, no new matter has been added and entry thereof is respectfully requested.

Regarding the Priority Application

Applicants respectfully do not concede the issue of priority for the claims for the reasons of record. In any event, in view of the cancelled claims, the amendments to the claims set forth above and the accompanying sworn Declaration under 37 C.F.R. §1.132, all grounds for rejection are moot and therefore, the claims are in condition for allowance.

I. REJECTIONS UNDER 35 U.S.C. §112, FIRST PARAGRAPH

The rejection of claims 121, 124, 145 and 148 under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement is respectfully traversed. The grounds for rejection are set forth in the Office Action, pages 4-14.

For the reasons of record, Applicants maintain that in view of the guidance in the specification and knowledge and skill in the art concerning antibody structure and function at the time of the invention, and that antibody variants having the requisite activity could be produced and identified using routine methods disclosed in the specification or that were known in the art at the time of the invention, one skilled in the art could make antibodies and antigen binding fragments that specifically bind to the recited polypeptide without undue

experimentation. Nevertheless, solely in order to further prosecution of the application and without acquiescing to the propriety of the rejection, Applicants have amended claims 121 and 124 and have cancelled claims 145 and 148 without prejudice. Applicants will therefore address the rejection as to amended claims 121 and 124

Amended claim 121 requires all three CDRs of each heavy and light chain variable regions sequence. Accordingly, as all three CDRs are present in the heavy and light chain variable region sequences, the ground for rejection of claim 121 is moot.

Amended claim 124 no longer recites the V_L, V_H, and F_C, fragments. Accordingly, the ground for rejection of claim 124 is moot.

In sum, the grounds for rejection are moot in view of the amendments to claims 121 and 124. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement be withdrawn.

The rejection of claims 117 to 119, 121, 141 to 143 and 145 under 35 U.S.C. §112, first paragraph as allegedly lacking an adequate written description is respectfully traversed. The grounds for rejection are set forth in the Office Action, pages 14-24.

Claims 117 to 119, 121, 141 to 143 and 145 prior to entry of this paper are adequately described for the reasons of record. Nevertheless, solely in order to further prosecution of the application and without acquiescing to the propriety of the rejection, claims 117 to 119, 141 to 143 and 145 have been cancelled herein without prejudice, and claim 121 has been amended as set forth above. The rejection will therefore be addressed with respect to amended claim 121.

Amended claim 121 requires all three CDRs of each heavy and light chain variable regions sequence. Accordingly, as all three CDRs are present in the heavy and light chain variable region sequences, the ground for rejection of claim 121 is moot.

In sum, the grounds for rejection are moot in view of the amendment to claim 121. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph, as allegedly lacking written description be withdrawn.

II. REJECTION UNDER 35 U.S.C. §102(b)

The rejection of claims 111 to 122 and 126 to 130 under 35 U.S.C. §102(b) as allegedly anticipated by Brandlein *et al.* (Amer. Assoc. Cancer Res. 43:970 abstract #4803 (2002)) as evidenced by Brandlein *et al.* (Human Antibodies 11:107 (2002)) is respectfully

traversed. Allegedly, Brandlein *et al.* describe each and every element claimed, as set forth on pages 24 to 26 of the Office Action.

Claims 111 to 122 and 126 to 130 are adequately supported by the priority application, as discussed in the record. Furthermore, Brandlein *et al.* (Amer. Assoc. Cancer Res. 43:970 abstract #4803 (2002)) is not enabling disclosure with respect to claims 111 to 122 and 126 to 130 and therefore cannot be properly cited under 35 U.S.C. §102. Nevertheless, solely in order to further prosecution of the application and without acquiescing to the propriety of the rejection, claim 121 has been amended as set forth above. The rejection will therefore be addressed with respect to the previously presented claims and amended claim 121.

Submitted herewith is a Declaration under 35 C.F.R. §1.132, executed by Drs Vollmers and Mueller-Hermelink which declares, among other things, that neither the PM-2 antibody nor the PM-2 producing hybridoma (deposit no. DSM ACC 2600) were available to the public prior to July 2, 2003, the filing date of international application no. PCT/IB2003/003487, which is the PCT application of the subject national phase application. In view of the executed Declaration under 35 C.F.R. §1.132, and that Brandlein *et al.* (Amer. Assoc. Cancer Res. 43:970 abstract #4803 (2002)) is not an enabling disclosure of claims 111 to 122 and 126 to 130, Applicants respectfully request that the rejection under 35 U.S.C. §102(b) be withdrawn.

III. REJECTION UNDER 35 U.S.C. §103(a)

The rejection of claims 124, 125, 148 and 149 under 35 U.S.C. §103(a) as allegedly obvious over Brandlein *et al.* (Amer. Assoc. Cancer Res. 43:970 abstract #4803 (2002)) in view of Taylor *et al.* (US Patent 5,001,225) is respectfully traversed. Allegedly, Brandlein *et al.* in combination with Taylor *et al.* teach or suggest each and every element claimed, as set forth on pages 26-30 of the Office Action.

Claims 124, 125, 148 and 149 prior to entry of this paper would not have been obvious in view of Brandlein *et al.* alone, or in combination with Taylor *et al.*, for the reasons of record. Nevertheless, solely in order to further prosecution of the application and without acquiescing to the propriety of the rejection, claims 148 and 149 have been cancelled herein without prejudice. The rejection will therefore be addressed only with respect to claims 124 and 125.

As stated above, in the executed Declaration under 35 C.F.R. §1.132, Drs Vollmers and Mueller-Hermelink declare that neither the PM-2 antibody nor the PM-2 producing hybridoma (deposit no. DSM ACC 2600) were available to the public prior to July 2, 2003, the filing date of international application no. PCT/IB2003/003487, which is the PCT application of the subject national phase application. Brandlein *et al.* (Amer. Assoc. Cancer Res. 43:970 abstract #4803 (2002)) is not an enabling disclosure of claims 124 and 125. Taylor *et al.* (US Patent 5,001,225) fail to teach or suggest each and every element of claims 124 and 125, let alone provide a reasonable expectation of success of producing an antibody or an antigen binding fragment of claims 124 and 125. Consequently, Applicants respectfully request that the rejection under 35 U.S.C. §103(a) be withdrawn.

IV. REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH

The rejection of claims 135 to 154 under 35 U.S.C. §112, second paragraph, as allegedly indefinite is respectfully traversed. The grounds for rejection are set forth in the Office Action, pages 30-31.

Claims 135 to 154 have been cancelled herein without prejudice. Accordingly, the rejection under 35 U.S.C. §112, second paragraph is moot and must be withdrawn.


CONCLUSION

In summary, for the reasons set forth herein, Applicants maintain that the claims clearly and patentably define the invention, respectfully request that the Examiner reconsider the various grounds set forth in the Office Action, and respectfully request the allowance of the claims which are now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (858) 509-4065. Please charge any fees associated with the submission of this paper to Deposit Account Number 033975. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Respectfully submitted,

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